REMARKS

Rejection of the claims under 35 USC §112:
Claims 5 and 13 have been rejected under 35 USC 112 as being indefinite. Applicants have canceled the claims to obviate the rejection.

Claims 1, 2, 4-6, 12-14, 18, and 22-22 have been rejected under 35 USC 112 for containing informalities. Applicants have amended claims 1 and 18 to obviate the objections. Specifically, Applicants have amended the claims as requested by the Examiner to more clearly set forth the relationship of the specific steps in the claims.

Double Patenting Rejection:
Claims 1, 2, 4-6, 12-14, 18, and 22-22 have been rejected under the judicially created doctrine of double patenting over claim 1-4 of U. S. Patent No. 6,627,616 B2. Applicants have amended the specification to obviate the rejection. Specifically, Applicants have amended the specification to make the instant application a continuation-in-part of nonprovisional U. S. Patent Application Serial No. 09/391,260, filed on Sep. 7, 1999, which is a division of application No. 09/975,573, filed on Nov. 21, 1997, now Pat. No. 6,265,387, which is a continuation of application No. 08/571,536, filed on Dec. 13, 1995, now abandoned. U. S. Patent No. 6,627,616 B2 is also a continuation-in-part of nonprovisional U. S. Patent Application Serial No. 09/391,260, filed on Sep. 7, 1999.

Rejection of the claims under 35 USC §102:
Claims 1, 2, 4-6, 12-14, 18, and 22-22 have been rejected under 35 USC 102(e) as being anticipated by Monahan et al. (US Patent 6,627616). Applicants believe the amendment to the specification should obviate the rejection of the claims under 35 USC 102(e).

Claims 1, 2, 4-6, 12-14, 18, and 22-22 have been rejected under 35 USC 102(f) because the applicant did not invent the subject matter. Applicants respectfully disagree. The inventors of '616 established the general process for intravascular delivery of nucleic acid. However, the inventors of the instant application invented the described heart process for specific delivery of nucleic acid to cardiac tissue.

The Examiner's objections and rejections are now believed to be overcome by this response to the Office Action. In view of Applicants' amendment and arguments, it is submitted that claims 1, 2, 4, 6, 12, 14, 18, and 22-22 should be allowable.

Respectfully submitted,

Mark K. Johnson Reg. No. 35,909
Mirus
505 South Rosa Road
Madison, WI 53719
608-238-4400

I hereby certify that this correspondence is being sent by facsimile transmission to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450 on this date: November 7, 2003.

Kirk Ekena

[REPLACEMENT SHEET]

A PROCESS FOR DELIVERING NUCLEIC ACIDS TO CARDIAC TISSUE

This application is related to prior provisional application 60/100,168 filed on September 14, 1998 and is a continuation-in-part of application No. 09/391,260, filed on Sep. 7, 1999, which is a division of application No. 09/975,573, filed on Nov. 21, 1997, now Pat. No. 6,265,387, which is a continuation of application No. 08/571,536, filed on Dec. 13, 1995, now abandoned.

FEDERALLY SPONSORED RESEARCH

This invention was made with United States government support from NIH Grant Number DK49117. The United States has certain rights in this invention.

Field of the Invention

The invention generally relates to techniques for delivering nucleic acids to a heart for purposes of gene therapy. More particularly, the invention involves vascular delivery of DNA and RNA to a heart for gene expression or gene regulation.

Background

Gene therapy is an approach to treating diseases based on the expression of genes toward a therapeutic goal. Gene therapy has been discussed in the context of treating diseases although it also has a potential for disease prevention.

A basic challenge in gene therapy is to develop approaches for delivering genetic material to the appropriate cells of a patient in a way that is specific, efficient and safe. This problem of "drug delivery," where the gene is a drug, is particularly challenging. If genes are appropriately delivered they can potentially lead to a cure. A primary focus of gene therapy is based on strategies for delivering genes.